CANNON BUILDING
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DOVER, DELAWARE 19904-2467

STATE OF DELAWARE

BOARD OF PHARMACY

TELEPHONE: (302) 744-4500
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APPLICATION FOR NON-RESIDENT PHARMACY PERMIT
INSTRUCTION SHEET

When to File Application

A pharmacy located outside Delaware must hold a Delaware Non-Resident Pharmacy permit in order to ship, mail, or deliver, in any manner, any controlled substance or prescription drug to a patient in Delaware (24 *Del. C.* §2535). Non-Resident Pharmacies must comply with Title 24, Chapter 25 of the *Delaware Code* when dispensing for Delaware clients.

File this application form when:

- Applying for an initial Delaware Non-Resident Pharmacy permit, or
- Re-applying after a previous Delaware Non-Resident Pharmacy permit has lapsed and is no longer renewable
- Applying for a new Non-Resident Pharmacy permit due to a change of ownership or controlling interest. (Permits are not transferable.) The application must be filed within 30 days of the ownership change.

This application form is *not* required when either of the following events occurs. In these situations, see **Reporting Non-Resident Pharmacy Change of Address or Name** below.

- Relocation of pharmacy or other address change where ***no*** change in controlling interest has occurred
- Name change where ***no*** change in controlling interest has occurred.

Important Information about Delaware Controlled Substances Registration

If the non-resident pharmacy dispenses controlled substances to patients in Delaware, a separate *Controlled Substances Application for Facilities* is required. If the non-resident pharmacy must file a new application or re-application for a Non-Resident Pharmacy permit (e.g., due to ownership change), a new application or re-application for controlled substance registration application is also required.

A pharmacy must have a Delaware Pharmacy permit, Delaware controlled substance registration and federal DEA permit before storing and/or dispensing controlled substances in Delaware.

Requirements for *All* Applications

These requirements apply to all applications, whether initial filing or re-application. Please read and follow instructions carefully. Failing to follow instructions will delay processing of your application.

☐ Submit completed, signed and notarized *Application for Non-Resident Pharmacy Permit*.
- Applications that are incomplete, unsigned or not notarized will be rejected.

☐ Arrange for the pharmacist-in-charge (PIC) to sign the **PHARMACIST-IN-CHARGE ACKNOWLEDGMENT** section.
- PIC changes must be reported to the Board of Pharmacy within 10 days of the change. Use the *Report of Pharmacist-in-Charge Change* form.
- The PIC of a Nuclear Pharmacy must be a Qualified Nuclear Pharmacist. He or she is responsible for all Pharmacy operations and must be personally on the premises at all times that the Pharmacy is open for business.
- To receive news and alerts from the Delaware Board, a current email address is *essential*. If the PIC is a Delaware-licensed Pharmacist, the PIC can keep all of his or her contact information up-to-date online at Change Contact Information. If the PIC is not Delaware-licensed, he or she can report contact information changes to the Board office by mail or email.

☐ Enclose the non-refundable processing fee by check or money order made payable to the "State of Delaware."
- Applications submitted without the required fee will be rejected.

☐ Enclose a copy of each permit, registration or license held by this pharmacy in the jurisdiction (state, U.S. territory or District of Columbia) where it is located and dispenses medications.

☐ Enclose a separate sheet showing the following information for *each* owner, corporate officer, pharmacist and non-registered pharmacy employee listed on the application:
- Name
- Date of Birth
- Mailing Address

☐ Enclose a **sample label** showing the pharmacy's toll-free number 24 *Del. C.* §2537(a)(4) *and* the following requirements from 24 *Del. C.* §2522(b):
- Prescription number
- The date the prescription is dispensed
- Patient's full name
- Brand or established name and strength of the drug to the extent that it can be measured
- Practitioner's directions as found on the prescription
- Practitioner's name
- Name and address of the dispensing pharmacy or practitioner

☐ Enclose a **sample patient profile** that meets the requirements of Section 5.0 of the Board's Rules and Regulations. ***Label*** ***each of the following required items on the sample profile:***
- ☐ Patient's family name and first name
- ☐ Patient's address and phone number (or location in institution)
- ☐ Patient's gender and age or date of birth
- ☐ Original date the medication is dispensed following receipt of the prescription
- ☐ Number or designation for prescription
- ☐ Prescriber's name
- ☐ Name, strength, quantity, directions and refill information of drug dispensed
  - Appropriate directions must also be present if medication is for patients in institutions.
- ☐ Initials of dispensing pharmacist and date of dispensing medication as a refill if those initials and date are not recorded on original prescription
- ☐ If patient refuses to give all or part of the required information, the pharmacist shall indicate and initial in the appropriate area
- ☐ Pharmacist comments relevant to the patient's drug therapy, including any other information peculiar to the specific patient or drug
- ☐ Annotate the patient's
  - allergies, idiosyncrasies, chronic diseases
  - frequently used over-the-counter medications

  If the answer is "none," this must also be shown on the profile.

☐ Enclose a copy of the most recent inspection report from the licensing agency of the jurisdiction where the pharmacy is located.

Reporting Non-Resident Pharmacy Change of Address or Name

You may report an address change or name change by letter *provided no change of ownership or controlling interest has occurred*. You must report the change within 10 days of its occurrence. When reporting, note the following:

☐ The letter should include:
- pharmacy name as it appears on current permit
- license number
- old information
- new information
- effective date of the change.

☐ Enclose duplicate license fee by check or money order made payable to the "State of Delaware." The duplicate license will reflect the new name and address.

If the pharmacy opens additional sites where medications will be dispensed, you must file an application for a permit for each additional business site.

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APPLICATION FOR NON-RESIDENT PHARMACY PERMIT

TYPE OF APPLICATION

1. Select the items that describe the reason for filing this application:

   ☐ This pharmacy has never held a Delaware Non-Resident Pharmacy permit.
   ☐ This pharmacy previously held Delaware Non-Resident Pharmacy permit number **A9-** _____ that has lapsed and is no longer renewable.
   ☐ This pharmacy's ownership has changed – Non-Resident Pharmacy permit number **A9-** _____

CONTACT AND LOCATION INFORMATION

2. Name of Business (as it should appear on license): _____

3. Enter all other trade or business names you use (or have used) such as "doing business as" or "formerly known as" names: _____ _____ _____

4. ***Dispensing Location* Address**: _____
   Street (*No PO Boxes*)

   _____ _____ _____
   City State Zip

5. Phone: _____ Required Toll-Free Number: (_____) _____

6. ***Mailing* Address** (*if different from physical location*): _____

   _____ _____ _____
   City State Zip

7. Enter the name and email of the person who should be directly contacted for information about this application. The contact may be an owner, a representative in the corporate/district office, or the Pharmacist-in-Charge. An *Application Receipt* and any other correspondence about this application will be sent to the email address entered here.

   Contact Name: _____ Email: _____

OWNERSHIP AND DESIGNATED AGENT INFORMATION

8. Type of Business Owner (check one):

   ☐ Sole Proprietor – Continue with Question 9.
   ☐ Individual with federal employee identification number – Continue with Question 9.
   ☐ Partnership – **Skip to** Question 10.
   ☐ Corporation – Enter Date of Corporate Charter: _____ State of Incorporation: _____
   Skip to Question 10.

9. Enter the following information about the owner and then skip to Question 11.

   Full Name: _____ Birth Date: _____

   Mailing Address: _____

   _____ _____ _____
   City State Zip

10. If a partnership, list ***all active partners***. If a corporation, list ***all principal officers***.

FULL NAME	TITLE

Enclose a separate sheet showing name, birth date, and mailing address for each person you listed above.

11. Each non-resident pharmacy must designate a *registered agent in Delaware* for service of process. (If no registered agent is named, then the Delaware Secretary of State is deemed the lawful representative.) Do you wish to designate an agent? Yes ☐ No ☐ If yes, enter the following information about the designee:

    Full Name: _____ Birth Date: _____

    Mailing Address: _____

    _____ _____ _____
    City State Zip

    Phone Number: _____ Email: _____

    Is this agent a Delaware-licensed pharmacist? Yes ☐ No ☐ If yes, enter Delaware license: **A1-** _____

12. Do you agree to notify the Board within 10 days of a change of ownership or registered agent? Yes ☐ No ☐

PHARMACIST AND EMPLOYEE INFORMATION

13. Enter the following information about the Pharmacist-in-Charge:

    Full Name: _____ Birth Date: _____

    Pharmacist License Number in jurisdiction where pharmacy is located: _____

    Mailing Address: _____

    _____ _____ _____
    City State Zip

    Is this person a Delaware-licensed pharmacist? Yes ☐ No ☐ If yes, enter Delaware license: **A1-** _____

    Arrange for the person named above to sign the *Pharmacist-in-Charge Acknowledgment* below.

PHARMACIST-IN-CHARGE ACKNOWLEDGMENT

I understand that I am responsible for conducting and managing the prescription department in compliance with all applicable state and federal laws.

Have you read and understood your responsibilities in Section 3.1 of the Board's Rules and Regulations? Yes ☐ No ☐

Do you agree to notify the Board of Pharmacy in writing within 10 days of your termination as pharmacist-in-charge? Yes ☐ No ☐

Pharmacist-in-Charge Signature: _____

Email: _____

To receive news and alerts from the Delaware Board, a current email address is *essential*.
If you are a Delaware-licensed Pharmacist, you can keep all of your contact information up-to-date online at Change Contact Information.
If you are not Delaware-licensed, mail or email contact information changes to the Board office

14. List all other registered pharmacists who will be dispensing at the pharmacy.

FULL NAME	LICENSE NUMBER IN JURISDICTION WHERE PHARMACY IS LOCATED

Enclose a separate sheet showing name, date of birth, and mailing address for each person you listed above.

15. List all unregistered employees who will be working in the pharmacy.

FULL NAME	EMPLOYMENT START DATE

Enclose a separate sheet showing name, date of birth, and mailing address for each person you listed above.

LICENSURE INFORMATION

16. Enter the following information about permits, registrations or licenses that this pharmacy holds in the jurisdiction (state, U.S. territory or District of Columbia) of the dispensing location above. If you need more room, enclose a separate sheet.

PERMIT TYPE (e.g., pharmacy, controlled substance)	PERMIT NUMBER	JURISDICTION	EXPIRATION DATE

Enclose a copy of each permit/license/registration listed above. Also, enclose a copy of the most recent inspection report from the licensing agency in the jurisdiction where the pharmacy is located.

17. Enter the pharmacy's federal (DEA) Controlled Substances Registration number for the jurisdiction where the pharmacy is located: _____

INFORMATION ABOUT PHARMACY SERVICES

18. Check all pharmacy services offered to Delaware patients:

- ☐ Dispense non-controlled substances
- ☐ Dispense controlled substances
- ☐ Sterile compounding – check all that apply:
  - ☐ LOW RISK
  - ☐ MEDIUM RISK
  - ☐ HIGH RISK
- ☐ Non-sterile compounding
- ☐ Wholesale distribution
- ☐ Pharmaceutical manufacturing
- ☐ Mail order
- ☐ Long-term care
- ☐ Nuclear
- ☐ Veterinary Medicine

19. Will you provide ***non-sterile*** compounding to Delaware patients? Yes ☐ No ☐ If yes, check all that apply:

- ☐ Pursuant to patient-specific prescription
- ☐ In bulk – compounding multiple doses from a single source or batch
- ☐ In bulk – for office use

20. Will you provide ***sterile*** compounding to Delaware patients? Yes ☐ No ☐ If yes, check all that apply:

- ☐ Pursuant to patient-specific prescription
- ☐ In bulk – compounding multiple doses from a single source or batch
- ☐ In bulk – for office use

21. Will you compound in bulk, whether sterile or non-sterile? Yes ☐ No ☐ If yes, indicate your largest number of doses from a single batch: ☐ 24 or fewer ☐ 24 – 49 ☐ 50 – 100 ☐ 100 or more

22. Will you provide ***sterile*** compounding to Delaware patients? Yes ☐ No ☐ If yes, check all types of substances compounded:

- ☐ Total parenteral nutrition (TPN)
- ☐ Parenteral antibiotics
- ☐ Parenteral electrolytes
- ☐ Irrigating fluids
- ☐ Parenteral analgesics
- ☐ Aqueous inhalant solutions for respiratory
- ☐ Parenteral antineoplastic agents
- ☐ Parenteral vitamins
- ☐ Ophthalmic preparations
- ☐ Other: _____

If a non-resident pharmacy compounds sterile drugs without a prescription and distributes them to Delaware, the pharmacy is an outsourcing facility as defined in Section 503B, *Registration of Outsourcing Facilities and Reporting of Drugs*, of the federal Food, Drug, and Cosmetics Act. *You must complete and submit an Application for Outsourcing Facility in addition to this application*.

INFORMATION ABOUT PHARMACY OPERATION

23. Does this pharmacy operate at least six days per week for at least 40 hours per week (24 *Del. C.* §2537(a)(4))? Yes ☐ No ☐

24. The area in which drugs and devices are stored must be accurately monitored using control devices to maintain room temperature between 59° and 86° Fahrenheit. Will the pharmacy have sufficient environmental control, i.e. lighting, ventilation, heating, and cooling, to maintain the integrity of drugs and devices? Yes ☐ No ☐

25. The sink in the pharmacy area must be large enough to accommodate the equipment required by the Board so that the utensils can be properly washed and sanitized. Will the pharmacy contain a sink with hot and cold running water? Yes ☐ No ☐

26. Refrigerators and freezers (where required) will be maintained at the USP/NF range: Refrigerator – 36 ° to 46 ° Fahrenheit; Freezer – minus 4 ° to plus 14 ° Fahrenheit. Will the pharmacy have suitable refrigeration with appropriate monitoring device? Yes ☐ No ☐

27. Briefly explain procedures used to transport medications that need special handling or temperature monitoring.

_____

_____

_____

28. Each pharmacy is required to maintain a library of the latest edition and supplements of current reference sources (either hard copy or electronic) appropriate to the practice and to the care of the patient served. Will the pharmacy meet this requirement? Yes ☐ No ☐ If yes, explain how you will assure that current information is readily available (e.g., FDA website): _____

_____

29. The pharmacy must maintain the following records:
    - the original of every prescription compounded or dispensed at the pharmacy for a period of at least three years
    - patient profile record for a period at least one year from the date of the last entry in the profile record unless it is also used as a dispensing record.

    Will the pharmacy meet these recordkeeping requirements (24 *Del. C*. §2537(a)(2), 24 *Del. C.* §2553)? Yes ☐ No ☐

30. When receiving a new prescription, a pharmacist (or pharmacy intern under the direct supervision of a pharmacist) must examine the patient profile before dispensing the medication to determine the possibility of a harmful drug interaction or reaction. If a potential harmful reaction or interaction is recognized, the pharmacist must take appropriate action to avoid or minimize the problem, including consultation with the physician as necessary. Will the pharmacy meet this requirement? Yes ☐ No ☐

Enclose the following samples:

- **sample label**
- **sample patient profile**

See the Instruction Sheet for checklists of the items that must appear on each sample.

DISCLOSURES

31. Have any of the owners, corporate officers, pharmacists or unregistered employees listed on this application ever been convicted of or entered a plea of guilty or *nolo contendere* (no contest) to any felony, misdemeanor or any other criminal offense, including any offense for which they have received a pardon, in any jurisdiction? Yes ☐ No ☐ **If yes, submit a certified copy of the criminal history record from any jurisdiction where they have been convicted or pardoned. For information on obtaining a Delaware criminal history record, see State Bureau of Identification.**

32. Are any of the owners, corporate officers, pharmacists or unregistered employees listed on this application presently charged with committing a felony? Yes ☐ No ☐ **If yes, explain in detail on a separate sheet**.

33. Have any of the owners, corporate officers or pharmacists listed on this application ever applied for a pharmacy permit or controlled substances registration in any jurisdiction and had the application denied? Yes ☐ No ☐ **If yes, explain in detail on a separate sheet.**

34. Has any of the owners, corporate officers or pharmacists listed on this application ever been the subject of any disciplinary action (formal or informal) by any federal or state agency or any hospital credentials committee including, but not limited to, revocation or suspension of a controlled substance registration or is any such action pending? Yes ☐ No ☐ **If yes, explain in detail on a separate sheet and enclose any relevant documents.**

DUTY TO REPORT

35. To obtain a Delaware permit as a Non-Resident Pharmacy, you must certify that the owners, corporate officers, pharmacists and unregistered persons listed on this application understand that they each have a ***mandatory*** obligation to file a written report with the Delaware Board of Medical Licensure and Discipline within 30 days if they have any reason to believe that a Delaware-licensed medical practitioner is (or may be) guilty of unprofessional conduct as defined in 24 *Del. C.* §1731 OR that he/she is (or may be):
    - medically incompetent
    - mentally or physically unable to engage safely in the practice of medicine
    - excessively using or abusing drugs including alcohol.

    I certify that the owners, corporate officers and pharmacists listed on this application have read the provisions of 24 *Del. C.* §1730, 24 *Del. C.* §1731 and 24 *Del. C.* §1731A and that they understand their *duty to report*. **Yes** ☐ **No** ☐

36. To obtain a Delaware permit as a Non-Resident Pharmacy, you must certify that the owners, corporate officers, pharmacists and unregistered persons listed on this application understand that they each have a ***mandatory*** obligation to make an immediate oral report to the Delaware Department of Services for Children, Youth and Their Families if they know of, or they suspect, child abuse or neglect under Chapter 9 of Title 16 and to follow up with any requested written reports.

    I certify that the owners, corporate officers and pharmacists listed on this application have read 16 *Del. C.* §903 and that they understand their *duty to report*. **Yes** ☐ **No** ☐

    When your application is complete, please allow 4-8 weeks to receive your permit. A complete application is one that includes all required documentation and correct payment. Applications that are not complete within 12 months of filing may be considered abandoned and discarded.

AFFIDAVIT

I certify that this Non-Resident Pharmacy complies with all lawful directions and requests for information from regulatory or licensing agencies of the jurisdiction where it is licensed and will comply with all such requests made by the Delaware Board pursuant to Delaware law and regulations. I further certify that this Non-Resident Pharmacy will maintain its records of prescription drugs dispensed to patients in Delaware so that the records are readily retrievable from the record of drugs dispensed for other patients. I hereby swear or affirm that all the foregoing statements are correct and do hereby agree to abide by the Pharmacy laws of the State of Delaware for non-resident pharmacies and to the rules and regulations of the Delaware State Board of Pharmacy as applicable to non-resident pharmacies.

Signature:_____ Date: _____

Print Name:_____ Position: _____

State: _____ County: _____

Sworn or affirmed before me a Notary Public this_____ day of _____ 2_____

Notary Public Signature: _____

SEAL

My commission expires on _____

APPLICATIONS THAT ARE NOT SIGNED, NOT NOTARIZED, INCOMPLETE OR NOT ACCOMPANIED BY THE REQUIRED FEE WILL BE REJECTED.